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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,599	02/28/2002	Brent R. Constantz	CRD5401USNP	7922

27777 7590 10/15/2008  
PHILIP S. JOHNSON  
JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
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VU, QUYNH-NHU HOANG

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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10/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/087,599	<b>Applicant(s)</b> CONSTANTZ ET AL.	
	<b>Examiner</b> QUYNH-NHU H. VU	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-54 is/are pending in the application.
- 4a) Of the above claim(s) 35-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23, 25-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Response to Amendment***

Amendment and Request for Continued Examination (RCE) filed on 7/07/08 has been entered.

Claims 1-23, 25-34 are present for examination.

Claim 24 is cancelled.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 recites the limitation "said target physiological site" in lines 5-6; Claim 12 recites the limitation "said target vascular site" in line 7; Claim 21 recites the limitation "said aortic valve" in lines 6 and 9. There are insufficient antecedent basis for this limitation in the claim.

As note that, those limitations above are in preamble. It is not considered as a positive language. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1-6, 9-14, 17-23, 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Urie (US 2001/0031943).

Urie discloses a device comprising: a fluid delivery element having a proximal and distal end; a compliant porous region 10, 11 at said distal end of the fluid target site; the porous region being formed from a compliant material (sponge material 11) and configurable into multiple shapes. For example: the sponge material is shrunk when absorbent material in the dry state; it is expanded when absorbent material in the wet state); an aspiration element 35

Since Applicant does not clearly explain the meaning of the word “compliant”. Examiner interprets “compliant” means something easy to flexible, soft and a porous material.

Regarding claims 11, 14, 17 and 28, the device further comprise a second fluid delivery element 41.

Regarding claims 12, 18 and 21, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., “...to contact target vascular site” of claim 12, the limitation “...to conform to a vascular structure” of claim 18; the limitation “...configured to fit inside of an aortic sinus of said aortic valve” and limitation “...to contact said aortic valve” of claim 21; the limitation “...for each different aortic sinus of said aortic valve” of claim 22, functional limitations, do not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

Regarding claim 23, an occlusion element is a plug 13.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 7-8, 15-16, 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urie in view of Nita et al. (US 5,997,497).

Urie discloses the invention substantially as claimed. Urie does not disclose the device includes an external energy, wherein the external energy element is a sonic energy element.

Nita discloses a catheter equipped and configured for drug delivery comprising: an external energy 14, 16; wherein the external energy is ultrasound transducer.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Urie with an external energy such as ultrasound transducer, as taught by Nita, in order to aid in rapidly dispersing, disseminating, distributing or atomizing the medicament.

Furthermore, it is very well-known in the art to provide the sonic energy (ultrasonic/ultrasound) in the medical art for delivering ultrasound to a target site. The Applicant also admitted the sonic energy application is well-known in the art (see para [46] of the Specification).

Claims 25-27, 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Urie in view of Nita and further in view of Stevens et al. (US 5,916,193).

Urie in view of Nita disclose the device as described above, but fails to explicitly disclose shunt and cap elements.

Regarding claim 31, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., the limitation "...configured to fit inside of an aortic sinus of said aortic valve; and the limitation "...to contact said aortic valve" of claim 31, functional limitations, do not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

Stevens et al. discloses a similar device with a plug occlusion element 674; a shunt 686 and a cap 690. See Figs. 4L-M.

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It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Urie in view of Nita by incorporating the plug, shunt and cap of the type, as taught by Steven, in order to isolate the region to which the fluid is to be delivered.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-23, 25-34 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763